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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,691	03/08/2004	Marc Bellotti	44378/293531 (13131-0331)	6082

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EXAMINER	
MONDESI, ROBERT B	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,691	BELLOTTI ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 27, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76,77 and 81-128* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76-77 and 81-128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 27, 2006 has been entered.

Status of the Claims

Claims 1-75 and 78-80 have been canceled. **Claims 76-77 and 81-128** are currently pending and under examination.

Information Disclosure Statement

The IDS filed May 24, 2007 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated below are withdrawn due to applicants' response in amendment filed March 27, 2006.

Maintenance of rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 76-77 and 81-128 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claims 73-78, 80 and 85-90** of copending Application No. 10996570.

The above rejections were explained in the previous Office action.

Response to applicants' arguments

In regards to the rejection of **claims 81-122** are on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claims 73- 78, 80 and 85-90** of copending Application No. 10996570, applicants have asserted when allowable subject matter is found, applicants will address the rejection by filing a terminal disclaimer.

New Rejections and objections

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 76-77 and 81-128 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

As indicated by the prior art rejections cited below, the product by process claims of the instant application are part of natural phenomena and are produced products of nature. The claimed composition of the invention containing delipidated HDL (pre-beta HDL) is produced by in the liver of animals via the mechanism of lipases or cholesteryl ester acceptors, see rejections under 35 U.S.C 102(b) below. Special note should be made of the fact that all the cited references refer to blood or blood plasma compositions wherein the LDL molecules have remained sufficiently the same for a period of time.

Federal courts have held that 35 U.S.C. 101 does have certain limits. First, the phrase "anything under the sun that is made by man" is limited by the text of 35 U.S.C. 101, meaning that one may only patent something that is a machine, manufacture, composition of matter or a process. See, e.g., Alappat, 33 F.3d at 1542, 31 USPQ2d at 1556; Warmerdam, 33 F.3d at 1358, 31 USPQ2d at 1757 (Fed. Cir. 1994). Second, 35 U.S.C. 101 requires that the subject matter sought to be patented be a ">new and< useful" invention. Accordingly, a complete definition of the scope of 35 U.S.C. 101, reflecting Congressional intent, is that any new and useful process, machine, manufacture or composition of matter under the sun that is made by man is the proper subject matter of a patent.

The subject matter courts have found to be outside >of, or exceptions to,< the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena. While this is easily stated, determining whether an applicant is seeking to patent an abstract idea, a law of nature or a natural phenomenon has proven to be challenging. These three exclusions recognize that subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomenon is not patentable. See, e.g., Rubber-Tip Pencil Co. v. Howard, 87 U.S. (20 Wall.) 498, 507 (1874) ("idea of itself is not patentable, but a new device by which it may be made practically useful is"); Mackay Radio & Telegraph Co. v. Radio Corp. of America, 306 U.S. 86, 94, 40 USPQ 199, 202 (1939) ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."); Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759 ("steps of locating' a medial axis, and creating' a bubble hierarchy . . . describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic abstract idea'").

The courts have also held that a claim may not preempt< ideas, laws of nature or natural phenomena. The concern over preemption was expressed as early as 1852. See Le Roy v. Tatham, 55 U.S. 156, 175 (1852) ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."); Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132, 76 USPQ 280, 282 (1948) (combination of six species of bacteria held to be nonstatutory subject matter).

Accordingly, one may not patent every "substantial practical application" of an idea, law of nature or natural phenomena because such a patent would "in practical effect be a patent on the [idea, law of nature or natural phenomena] itself." Gottschalk v. Benson, 409 U.S. 63, 71-72, 175 USPQ 673, 676 (1972).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 76-77 and 81-128 rejected under 35 U.S.C. 102(b) as being anticipated by Kunitake et al., 1992.

The claims of the present application are product by process claims drawn to the conversion of a composition containing alpha HDL (lipidated, as in containing cholesterol or at least one phospholipid) to a composition containing pre-beta HDL (delipidated, as in having lower content of at least one phospholipid or cholesterol) wherein the cholesterol or phospholipid content of LDL particles in the composition remains the same; "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Kunitake et al. teach that the focus of their study was to monitor the inter-conversion of pre-beta HDL and alpha HDL in blood serum (page 1808, column 2, paragraph 3, lines 4-9).

Kunitake et al. disclose a model for the conversion of serum alpha HDL to Pre-beta HDL wherein cholesterol is removed from alpha HDL via cholesteryl ester acceptors (page 1813, Fig. 10).

It is important to note that the according to the applicants own submissions in the specification, on page 2, lines 27-30 that Apo-A1 and Apo-A2 , Apo C (CI-III) Apo D and Apo E are found in HDL

Thus Kunitake et al. teach all the elements of **claims 76-77 and 81-128** and these claims are anticipated under 35 USC 102(b).

Claims 76-77 and 81-128 rejected under 35 U.S.C. 102(b) as being anticipated by Sviridov et al. 2002.

The claims of the present application are product by process claims drawn to the conversion of a composition containing alpha HDL (lipidated, as in containing cholesterol or at least one phospholipid) to a composition containing pre-beta HDL (delipidated, as in having lower content of at least one of phospholipids or cholesterol) wherein the cholesterol or phospholipids content of LDL particles in the composition remain the same; "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art,

the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Sviridov et al. teach that since HDL comprises of a number of minor and major subspecies, probably having different functional roles, the effective flux of cholesterol through RCT clearly requires coordinated metabolic regulation of HDL species and cholesterol. Small discoid lipid-poor particles, preβ$_1$-HDL, are an initial acceptor of cellular cholesterol. Upon accumulation of cholesterol these particles are transformed into bigger particles, preβ$_2$-HDL, which are a substrate for LCAT. Esterification of cholesterol in preβ$_2$-HDL and probably acquisition of additional apoA-I molecules lead to the formation of spherical α$_3$-HDL particles. These particles acquire more cholesterol from preβ-HDL and possibly also from cells that transforms these particles into larger α$_2$-HDL and α$_1$-HDL. The next step involves exchange of accumulated cholesteryl esters for triglycerides through the action of CETP, transfer of phospholipid through the action of phospholipid transfer protein (PLTP) and hydrolysis of triglyceride and phospholipid by HL. As a result, particles are remodeled into smaller α$_3$-HDL particles and lipid-free apoA (page 248, Figure 1).

It is important to note that the according to the applicants own submissions in the specification, on page 2, lines 27-30 that Apo-A1 and Apo-A2 , Apo C (CI-III) Apo D and Apo E are found in HDL

Thus Sviridov et al. teach all the elements of **claims 76-77 and 81-128** and these claims are anticipated under 35 USC 102(b).

Claims 76-77 and 81-128 rejected under 35 U.S.C. 102(b) as being anticipated by Barrans et al. 1994.

The claims of the present application are product by process claims drawn to the conversion of a composition containing alpha HDL (lipidated, as in containing cholesterol or at least one of the phospholipids) to a composition containing pre-beta HDL (delipidated, as in having lower content of at least one of phospholipids or cholesterol) wherein the cholesterol or phospholipids content of LDL particles in the composition remain the same; "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Barrans et al. teach that in order to verify a possible origin of pre-beta particles during the catabolism of high density lipoprotein, (HDL,) by hepatic lipase using two different models. A rat liver perfusion of native human HDL, in the presence of heparin induced, after 30 min, the formation of the pre-beta HDL subspecies. Human HDL, enriched with triacylglycerols, perfused in the same conditions, led after 15 min to an enhanced production of pre-beat HDL population, as compared with the results obtained with native HDL. A reduction of the alpha HDL, fraction was also evident. After perfusion, a similar formation of pre-beat HDL from triacylglycerol-rich HDL, was

observed in absence of heparin. When these HDL, were incubated in vitro for 120 min at 37 degrees in the presence of partially purified rat hepatic lipase, the appearance of pre-beta HDL was again found and associated with a decrease in size of the remaining alpha HDL subfractions as compared with original HDL (page 11572, abstract).

It is important to note that the according to the applicants own submissions in the specification, on page 2, lines 27-30 that Apo-A1 and Apo-A2 , Apo C (CI-III) Apo D and Apo E are found in HDL.

Thus Barrans et al. teach all the elements of **claims 76-77 and 81-128** and these claims are anticipated under 35 USC 102(b).

Conclusion

No claims are allowed

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B Mondesi
Examiner
Art Unit 1652
Robert B. Mondesi
6-5-2007